

3551. Misbranding of Hydr-Oxy-Colon device. U. S. v. 1 Device \* \* \* (and 5 other seizure actions). (F. D. C. Nos. 30923, 31341, 31376 to 31379, incl. Sample Nos. 90020-K, 90021-K, 15777-L to 15781-L, incl.)

**LIBELS FILED:** April 17 and July 12 and 24, 1951, District of Kansas.

**ALLEGED SHIPMENT:** On or about June 19 and 30, July 8, 10, 12, and 24, August 26, and September 15, 1950, from Dallas, Tex., Miami, Okla., and Hollywood, Calif., by or for the United X-Ray & Equipment Co., Inc., of Hollywood, Calif.

**PRODUCT:** 7 *Hydr-Oxy-Colon* devices at Garden City, Liberal, Pratt, Medicine Lodge, Jamestown, and Junction City, Kans., together with certain printed and graphic matter, namely, a number of booklets entitled "DeWelles 'Detoxa-colon' Oxygen Therapy," "Our Logical and Cooperative Clinic Plan," treatment charts bearing directions for treating numerous organs and disease conditions with the device, a leaflet entitled "Compare! The Normal Colon With Cases Pictured Below," and copy for use in preparing newspaper advertising and postal cards.

The devices were designed for administering mixed oxygen and water as an enema or vaginal douche.

**RESULTS OF INVESTIGATION:** Each of the devices was delivered to the consignees pursuant to agreements with the United X-Ray & Equipment Co., Inc., of Hollywood, Calif. When received by the consignees, the name plate on a number of the devices bore the name "Detoxacolon." These name plates were removed from the devices after delivery to the consignees, by representatives of the United X-Ray & Equipment Co., Inc., and replaced with a plate bearing the designation "Hydr-Oxy-Colon."

At the time the contracts were entered into with the company, its representatives supplied the purchasers with suggested copy for newspaper advertising and suggested copy for postal cards announcing free examinations by the consignees, assisted by a diagnostic specialist from Los Angeles, Calif. Reference was made to "New Colon Oxygen Therapy" on the postal card and "Oxygen Therapy" and "This New Colon Therapy, Which Embodies The Use Of Pure Oxygen and Water" in the newspaper advertisement. In each instance, the consignee delivered to a local newspaper the copy for the newspaper advertisement.

In accordance with the contract, a clinic was held in the office of each consignee, at which a representative of the United X-Ray & Equipment Co., Inc., was present. The booklets, leaflets, and treatment charts were furnished to the consignees by the company's representatives either at the time the agreement between the company and the consignees was made or at the time of the delivery of the devices or the holding of the clinic.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements and designs in the labeling accompanying the device were false and misleading. The statements and designs represented and suggested that the device was an adequate and effective treatment for allergy, asthma, hay fever, diabetes, arthritis, rheumatism, and high and low blood pressure; disorders of the kidney, ear, eustachian tube, eyes, thyroid, gall bladder, male and female reproductive organs, urinary bladder, pituitary, thymus, skin, rectum, lung, pancreas, adrenals, ovaries, testes, and colon; ptosis of liver, stomach, and colon; headaches, parasitic infestations, mineral deficiency, calcium deficiency, neuritis, colitis, including ulcerative and spastic types, varicosities,

stomach ulcers, heart conditions, including functional disorders, angina pectoris, partial heart block, and arrhythmias, spasticity of rectum, extreme ulceration of lower bowel, common cold, acute and chronic coryza, sinusitis, dysentery, amebic dysentery, flaccid condition of sphincters, anemia (pernicious and secondary), epilepsy, toxemias of pregnancy, infections and inflammations of female reproductive organs, prolapse of rectum and sigmoid, and enlargement of spleen and liver; that the device was an excellent treatment following childbirth; that it would eliminate distress and disease and would correct chronic ailments or pathological changes and bring about a restoration of health; and that the device was effective in the treatment of intestinal influenza, nausea, vomiting, extreme weakness, loss of weight, numerous daily bloody stools, displaced colon, projectile vomiting, inability to retain liquids, cancer, intestinal contraction, and adhesions. The device was not an adequate and effective treatment for such disease conditions, and it was not capable of fulfilling the promises of benefit made for it.

Further misbranding, Section 502 (j), the article was dangerous to health when used with the frequency and duration prescribed, recommended, and suggested in the accompanying booklet entitled "DeWelles 'Detoxacolon' Oxygen Therapy," as follows:

"Vaginal Therapy The vaginal treatment is given for infections and inflammatory diseases of the female pelvis, and is unexcelled in the results obtained by exposing the mucous membrane to the bactericidal effects of Oxygen. The continuous flow of Oxygen and water coming into contact with the tiny million folds in the mucous membrane of the vaginal wall and cervix with its countless millions of capillaries, is stimulating and thoroughly cleanses each cell of this membrane. This produces an extremely rapid destruction of such organisms as the trichomonadiae vaginalis, B. coli Staphylococcus and Streptococcus, which are the organisms usually found in these inflammatory conditions as well as cervical erosions. These conditions are usually manifest by vaginal discharges and tenderness in the pelvis upon pressure. The debris that is loosened by the action of this treatment, the secretion from stimulated mucous gland activity and the necrotic tissue fragments and shreds are carried away due to the action of the water during treatment. They are not left in the vaginal vault to further decompose or cause further inflammation and infection and which is equally serious—toxic absorption into the blood stream. This is in definite contrast to any other type of treatment now existing, and it produces a wholesome and exhilarating reaction upon all whom are fortunate enough to have this treatment. The only Contra-Indication for the vaginal treatment is during the early months of pregnancy. It is an excellent treatment following childbirth, as the tonus of these muscles is returned to normal much faster than in the usual period of time.

INSTRUCTIONS FOR VAGINAL THERAPY PROCEDURE: \* \* \* The operator \* \* \* inserts the vaginal applicator \* \* \* The suggested treating time is 20 to 25 minutes \* \* \* Turn the water control valve about a quarter of a turn and adjust the temperature until 100° F. is reached. \* \* \* Rapidly increase the temperature until tolerance has been reached, usually 115° F. for the first treatment. \* \* \* establish a two (2) liter flow \* \* \* Treat on the Hot water at tolerance for five (5) minutes \* \* \* Turn the thermostat to the Cold until a temperature of 90° F. has been reached, and repeat the above procedure \* \* \*. In cases where the vaginal area is highly inflamed, it may be necessary for the first few treatments to raise the temperature to 95° F. \* \* \*. Treat for five (5) minutes on the Cold water. Rise the temperature again as rapidly as possible to the tolerance of patient, or back to 115° F., and repeat the treatment on the Hot water for five minutes then reduce to the Cold water and repeat treatment. The temperature should then be brought back to 100° F. and left running for a minute or so. \* \* \* we advise giving three (3) treatments per week \* \* \* keep in mind always the pathology of the case and the degree of infection present before lowering the temperature to 80° F."

The device was dangerous since in the post partum period and in the acute stages of vaginal infections, treatment as directed would force infective material into or through the cervical canal, resulting in ascending infection with probable serious consequences to the health of the patient.

The device was alleged to be misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

**DISPOSITION:** June 19 and September 24, 1951. Default decrees of condemnation. The court ordered that two of the devices be delivered to the Food and Drug Administration and that the remainder be destroyed.

#### NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3552. TB-1 tables. U. S. v. 4,682 Bottles, etc. (F. D. C. No. 30311. Sample No. 35716-K.)

**LIBEL FILED:** December 8, 1950, Northern District of California; amended libel filed May 31, 1951.

**ALLEGED SHIPMENT:** On or about April 24 and 26, and September 11, 1950, the American Cyanamid Co., Calco Chemical Div., Bound Brook, N. J., shipped to itself in Los Angeles, Calif., a quantity of TB-1 powder. On or about September 15 and 20, 1950, the powder was sold to a firm in San Francisco, Calif., which firm had it tableted and packed into bottles.

**PRODUCT:** 4,682 bottles of *TB-1 tablets* at San Francisco, Calif., together with a number of accompanying leaflets entitled "Reference Manual 601 TB1-PSL The New Antituberculous Drug."

**LABEL, IN PART:** (Bottle) "100 Tablets—1050 TBI-PSL \* \* \* 50 Mgm. Per Tablet."

**NATURE OF CHARGE:** Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

**DISPOSITION:** August 28, 1951. The claimant having indicated that it did not desire to contest the matter, judgment of condemnation was entered and the court ordered that the product be destroyed.

#### DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\*

3553. Action to enjoin and restrain violations of Section 301 (a) with respect to male and female hormones. U. S. v. Hudson Products Co. (Maywood Pharmacal Co.), and Allen H. Parkinson. Tried to the court. Judgment denying application for permanent injunction reversed upon appeal. (Inj. No. 218.)

**COMPLAINT FILED:** September 29, 1949, Southern District of California, against the Hudson Products Co., a corporation, Long Beach, Calif., also trading under the name of the Maywood Pharmacal Co., at Hollywood, Calif., and against Allen H. Parkinson, president of the Hudson Products Co.

**ALLEGED VIOLATION:** The complaint alleged that the defendants were distributors of certain *male and female hormones*; that the *male hormones* consisted of *methytestosterone tablets* (10 milligrams), *methytestosterone linguets*

\*See also No. 3550.